

File No: BIO/CT/20/000072
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Biological Division)

FORM CT-06

(See rules 22, 25, 26, 29 and 30)

PERMISSION TO CONDUCT CLINICAL TRIAL OF NEW DRUG OR INVESTIGATIONAL NEW DRUG

The Central Licencing Authority hereby permits Mr. Varma B S S S Bhupathiraju of M/s Biological E Limited, Plot No 1, S.P. Biotechnology Park, Phase II, Kolthur Village, Shameerpet Mandal (India) -500078, Telephone No.: nil, Fax: nil, E-Mail: varma.bhupathiraju@biological.com to conduct clinical trial of the new drug or investigational new drug as per Protocol No.: BECT061/PCV-Phase-III/CTP-01, Version No.: 1.0 Final dated 14.05.2020 in the below mentioned clinical trial sites.

CT No.: CT- 18/2022

2. Details of new drug or investigational new drug and clinical trial site [As per Annexure].
3. This permission is subject to the conditions prescribed in part A of Chapter V of the New Drugs and Clinical Trials Rules, 2019 under the Drugs and Cosmetics Act, 1940.

Place: New Delhi
Date: 08-SEP-2022

(Dr. V. G. Somani)
Drugs Controller General (India)
Central Licencing Authority

Annexure: Details of New Drug or Investigational New Drug:

Name of the new drug or investigational new drug:	Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) (14 Valent)	
Therapeutic class:	Vaccine	
Dosage form:	Suspension for Intramuscular injection	
Composition:	Each dose of 0.5 ml contains	
	Name of Active ingredient	Quantity
	Pneumococcal Polysaccharide Serotype 1	3.0 µg
	Pneumococcal Polysaccharide Serotypes 3, 4, 5, 7F, 9V, 14, 18C, 19A, 19F, 22F, 23F and 33F	2.2 µg
	Pneumococcal Polysaccharide Serotype 6B	4.4 µg
	Name of Inactive ingredients	
	Adsorbed onto Aluminum Phosphate, as Al ⁺⁺⁺	≤ 0.75 mg
	Succinic Acid	147.5 µg
	2-Phenoxyethanol	4 mg
	Polysorbate 20	0.175 mg
	0.6% w/v Sodium Chloride Solution	q. s.
*Polysaccharides conjugated to 20 –50 µg of CRM ₁₉₇		
Indications:	For active immunization for the prevention of disease caused by <i>Streptococcus pneumoniae</i> serotypes 1, 3, 4, 5, 6B, 7F, 9V, 14, 18C, 19A, 19F, 22F, 23F and 33 F in infants ages 6-8 weeks at first dose. Dose schedule: 6 weeks, 14 weeks and 9 months of age (2+1)	

Details of clinical trial sites-

S. No.	Name and Address of Clinical Trial Site	Ethics Committee details	Name of Principal Investigator
1	King George Hospital, Andhra Medical College, Visakhapatnam –530 002.	Institutional Ethics Committee, King George Hospital, Maharani pet, Collector office Junction, Visakhapatnam-530 002, India. ECR/197/Inst/KGH/2013/RR-20	Dr. P. Venugopal
2	Guru Teg Bahadur Hospital, Dilshad Garden, North East Delhi –110 095, India.	Guru Teg Bahadur Ethics Committee, Guru Teg Bahadur Hospital, Dilshad Garden, North East Delhi -110 095. ECR/510/Inst/DL/2014/RR-17	Dr. Manish Narang
3	Cheluvamba Hospital, Mysore Medical college and Research, Institute, Irwin Road, Mysore - 570001, Karnataka.	Institutional Ethics Committee, Mysore Medical college and Research Institute, Dept. of Pediatrics, Irwin Road, Mysuru, Karnataka -570001. ECR/134/Inst/KA/2013/RR-19	Dr. S. Pradeep
4	Prakhar Hospital Pvt Ltd, 8/219 Arya nagar, Kanpur 208002.	Ethics Committee Prakhar Hospital Private Ltd.8/219 Arya Nagar, Kanpur-208002Uttar Pradesh, India ECR/1017/Inst/UP/2017	Dr. V. N Triapthi
5	Sant Dnyaneshwar Medical Education Research Center, 695/A, Sadashiv Peth, Opp. Vijay Talkies, Laxmi road, Pune-411030.	Institutional Ethics Committee. Sant Dnyaneshwar Medical Education Research Centre, 695/A, Sadashiv Peth, Opposite Vijay Talkies, Laxmi Road, Pune-411030 ECR/127/Inst/MH/2013/RR-19	Dr. Asish Dhongade

In addition to point 3, the permission is subject to following conditions:

- I. The clinical trial should be conducted as per approved protocol titled "A single blind randomised active-controlled Phase-III study to evaluate immunogenicity, safety, tolerability of a candidate 14-valent Pneumococcal Polysaccharide conjugate vaccine administered to 6-8 weeks old Indian Infants at 6 weeks, 14 weeks and 9 months of age (2+1 alternative dosing schedule)" vide Protocol No.: BECT056/PCV-Phase-III/CTP-01 Version No.: 1.0 Final dated 14.05.20.
- II. Firm is required to submit the copy of valid Insurance Certificate (certificate only) before initiation of subject trial.
- III. The firm is required to constitute a DSMB to review the safety data.
- IV. The formulation intended to be used in the clinical trial shall be manufactured under GMP conditions using validated procedures and shall have ongoing stability programme.
- V. Only CDL, Kasauli certified batches shall be used in the clinical trial.

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